IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

THE CITY OF HUNTINGTON, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, et al., Defendants.	Civil Action No. 3:17-01362 Hon. David A. Faber
CABELL COUNTY COMMISSION, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, et al., Defendants.	Civil Action No. 3:17-01665 Hon. David A. Faber

REPLY MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE EXPERT TESTIMONY FROM DR. MICHAEL SIEGEL REGARDING PURPORTED OPIOID "OVERSUPPLY"

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INTRODUCTION

Plaintiffs' response glosses over the shortcomings in Dr. Michael Siegel's proffered opinions and instead reverts to a discussion of largely irrelevant and unnecessary issues that do not address the larger problems identified in Defendants' motion—namely, that Dr. Siegel is unqualified to offer opinions about a purported "oversupply" of opioids, and his methodology and opinions are entirely unreliable and should be excluded.

As for Dr. Siegel's qualifications, Plaintiffs suggest that his public health experience studying alcohol, tobacco, and firearms is essentially the same as—and allows him to opine about—prescription opioids. This argument misses the point. Defendants' position is not that Dr. Siegel is unqualified to offer any opinions about prescription opioids at all; rather, it is that Dr. Siegel is unqualified to offer the specific opinions he has proffered on "oversupply" and distributor obligations, both of which require industry-specific knowledge about opioid distribution that Dr. Siegel does not have.

As for Dr. Siegel's methodology, Plaintiffs ignore the facts that undercut both his estimate about the size of the population served by each of the five pharmacies he studied in and around Cabell County and the City of Huntington and the nationwide benchmark he used to gauge the purported "oversupply" of prescription opioids to each of those pharmacies. Instead, Plaintiffs focus on irrelevant issues like the accuracy of Census data for calculating population size, and Dr. Siegel's own *ipse dixit* regarding the percentage of adults who used prescription opioids for purposes of calculating the threshold. Neither of these arguments respond to the fundamental flaws in Dr. Siegel's methodology that undermine the reliability of the conclusions he draws.

With respect to those conclusions, Plaintiffs similarly try to distract from Dr. Siegel's opinion about "oversupply." Rather than identifying a single other expert that has conducted a similar "oversupply" analysis (which they cannot), Plaintiffs instead simply ignore Dr. Siegel's

flawed methodology and suggest that because "oversupply" is a concept that has been discussed in the literature, then Dr. Siegel's made-for-litigation methodology on this topic must be reliable. That is not so.

Finally, with respect to Dr. Siegel's legal conclusions about Distributors' purported "public health responsibility" to prevent "oversupply," Plaintiffs engage in a game of semantics by contending that a "responsibility" is not the same as a legal duty. Again, that is not accurate. Plaintiffs' own response refers to Dr. Siegel's opinion as relating to the appropriate "standard of care," and other courts have excluded similar "standard of care" testimony from Dr. Siegel in the past. But even if Dr. Siegel's opinion were not a legal conclusion, his "public health responsibility" opinion still must be excluded because it is entirely unsupported and therefore unreliable and inadmissible.

Plaintiffs cannot avoid these serious methodological flaws in Dr. Siegel's opinions by saying that this can all be handled through cross-examination. Rule 702 does not permit the admission of unreliable expert testimony, whether or not cross-examination could expose that unreliability. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993) (trial judge "must ensure" that expert evidence "admitted is not only relevant, but reliable"). Since the methodological flaws of Dr. Siegel's opinions are clear (and essentially undisputed), the proper answer under Rule 702 is exclusion rather than permitting valuable trial time to be taken up with unreliable expert testimony.

ARGUMENT

A. Dr. Siegel Lacks The Required "Specialized Knowledge" Regarding Opioids And Therefore Is Not Qualified To Opine About Opioid "Oversupply" Or Distributor Obligations

It is undisputed that Dr. Siegel lacks relevant experience with the specific, novel opinions he offers about Defendants in this case: namely, that they "oversupplied" opioids to pharmacies,

and that in doing so, they violated a public health responsibility. But Plaintiffs ignore this fact, and instead overstate Dr. Siegel's qualifications related to opioids, opioid addiction, and distributors' obligations. They then incorrectly argue that his experience related to tobacco, alcohol, and firearms is sufficient to meet *Daubert*'s qualification requirement. It is not. Dr. Siegel's opinions require industry-specific knowledge about opioid distribution that he does not have—and Plaintiffs do not argue otherwise. Moreover, Dr. Siegel's experience with other addictive substances is irrelevant, because he is not opining about the addictive nature of opioids.

As Defendants have shown, Dr. Siegel's lack of relevant qualifications is evident from his own deposition testimony and the face of his report. He has never worked at the DEA, FDA, a pharmaceutical distributor, or a pharmacy; he has never before analyzed alleged "oversupply" by distributors or pharmacies, and he has never held himself out as an expert in the public health responsibilities of distributors. Ex. B at 62:21-63:9, 65:11-17, 78:8-12. In terms of his qualifications as an epidemiologist, Dr. Siegel's focus has been almost exclusively on harms related to tobacco, alcohol, and firearms. He simply has no relevant experience related to the novel opinions he offers in this case.

Plaintiffs insist that this lack of relevant experience does not matter. Instead, they argue that it is sufficient that Dr. Siegel has experience as an epidemiologist in the realm of "chronic disease epidemiology" and "substance abuse and addiction." Resp. at 4. In support, they point to his "first-hand experience treating several hundred patients for opioid addiction," and the fact that "he teaches public health students about the opioid epidemic virtually every semester." *Id.* Neither of these vague assertions should carry any weight as they relate to the Court's Federal Rule of Evidence 702 analysis, for several reasons.

First, experience with certain "public health" topics, even ones that relate to "substance abuse and addiction," is insufficient to render Dr. Siegel qualified to opine about the specific opioid-related topics he addresses in this case, particularly opioid "oversupply" and distributors' public health responsibilities. *See Lawrence v. Raymond Corp.*, No. 09 CV 1067, 2011 WL 348324, at *4 (N.D. Ohio Aug. 4, 2011) (citation omitted) ("[A] party cannot qualify as an expert generally by showing that the expert has specialized knowledge or training which would qualify him or her to opine on some other issue."); *Kumho Tire Co. v. Charmichael*, 526 U.S. 137, 156 (1999). Even Dr. Siegel acknowledged that tobacco, alcohol, and firearms are materially different products than opioids. Ex. B at 86:11-20; 88:1-89:21. And in any event, Dr. Siegel is not offering opinions about substance abuse or addiction.

Second, Plaintiffs' argument based on *AVX Corp. v. United States*, 518 F. App'x 130, 134-35 (4th Cir. 2013), for the proposition that Dr. Siegel's experience on health topics outside the opioid context is sufficiently specific to qualify him as an expert fails for a similar reason. The expert in *AVX* was a hydrogeologist with a subspecialty in groundwater contamination, but not with the particular chemical at issue in that case. *Id.* The court allowed the expert in that case to testify by finding that he had "extensive experience in ... and understood how contaminants—including the chemical in question—move[] in groundwater." *Id.* at 134 (internal quotation marks omitted).

Dr. Siegel's expertise, by contrast, is not a question of "subspecialties." Instead, his experience lies in an entirely different realm—the use and abuse of alcohol, tobacco, and firearms. Dr. Siegel acknowledged that these products are materially different from opioids, in particular because there is no meaningful medical use for alcohol, tobacco, or firearms, Ex. B at 88:13-15, and the supply and distribution of opioids is unlike anything related to alcohol, tobacco, or

firearms. *Id.* at 88:1-89:1. Indeed, Dr. Siegel admitted that he has never conducted the same "oversupply" analysis as part of his study for alcohol, tobacco, and firearms because there is no way to do so given the supply chain for those products (as opposed to prescription opioids). *Id.* at 89:2-21.

Third, and perhaps most tellingly, Plaintiffs offer only two vague examples of Dr. Siegel's experience with opioids. They first claim he has experience "treating several hundred patients for opioid addiction." Resp. at 4. Even setting aside that this "experience" all occurred prior to 1995, treating patients for opioid addiction and inventing a methodology to determine "oversupply" are not closely related. Next, Plaintiffs make the vague assertion that "he teaches public health students about the opioid epidemic virtually every semester." *Id.* But Dr. Siegel's own testimony makes clear that his classroom instruction does not relate to the topics on which he purports to opine. In fact, Dr. Siegel testified that his classes have never focused on distributors, that he has discussed distributors for no more than a couple of minutes in his classes, and that he has never taught specifically on the public health responsibilities of distributors. Ex. B at 84:17-85:3. Dr. Siegel offered no evidence that he has ever taught about the "oversupply" analysis he performs in this case.[1]

For an expert to be qualified under *Daubert*, they must have more than a general knowledge of the topic to be discussed. As shown, Dr. Siegel's passing familiarity with opioids and with the opioid crisis do not qualify him to provide a made-for-litigation analysis on "oversupply" and distributors' public health responsibilities.

[1] Dr. Siegel further testified that he did not believe he had any syllabi, classroom presentations, or class notes that describe his teaching on the opioid epidemic, making it nearly impossible to ascertain exactly what opioid-related topics Dr. Siegel has covered in his courses. Ex. B at 82:23-83:16.

B. Dr. Siegel's Methodology Is Unreliable

Plaintiffs provide no effective answer to the two core flaws in Dr. Siegel's methodology: the size of the populations allegedly served by the pharmacies Dr. Siegel discussed in his report, and the nationwide benchmark he used as a threshold for what constitutes "oversupply."

Estimates about the population served. Plaintiffs first try to justify Dr. Siegel's use of U.S. Census data to estimate the populations of the communities in which each of the pharmacies sit. But Defendants' arguments do not hinge solely on overall Census data. Instead, Defendants identified several factors that Dr. Siegel should have—but did not—consider in order for his analysis to be reliable, including geographic location, whether the population of that geographic location was likely to be undercounted in the Census (including data that evaluates precisely this question), movement of people through the towns in which the pharmacies are located, and their proximity to large hospitals. MOL at 8-12. These factors, taken together, greatly increase the size of the population served by a given pharmacy, and Plaintiffs do not argue otherwise. By not taking these factors into account, Dr. Siegel assumed that there was a much higher per-person number of dosage units being distributed to the pharmacies he studied. This flawed, unreliable methodology ultimately led him to the wrong conclusion—that the distributors exceeded the assumed nationwide threshold for "oversupply."

Rather than addressing these factors and demonstrating why they do not undermine the reliability of Dr. Siegel's opinion (they do), Plaintiffs simply gloss over them, and argue that these shortcomings in the analysis can be addressed on cross-examination. Resp. at 9. But this argument ignores *Daubert*'s gatekeeping standards—Plaintiffs' proffered expert must meet the requirements of reliable expert testimony in order to be admitted. Dr. Siegel's guesses related to the population served by the pharmacies in question fail to cross that threshold, rendering his opinions unreliable. *See Oglesby v. Gen. Motors Corp.*, 190 F.3d 244, 250 (4th Cir. 1999) (recognizing that reliable

expert testimony must be based on more than "belief or speculation") (citing *Daubert*, 509 U.S. at 592-93). Put another way, cross-examination is not a fix for an expert whose opinion is unreliable under *Daubert*.

Plaintiffs also argue that using a town's population as a stand-in for the population served by a particular pharmacy was proper because "Dr. Siegel was careful to only estimate the population ... when ... only one pharmacy served that town." Resp. at 9. But that argument only highlights the arbitrariness of Dr. Siegel's methodology. Dr. Siegel himself admits his methodology cannot be applied to larger cities.[2] And Plaintiffs' acknowledgment that the methodology is so arbitrary that it can only be applied to tiny single-pharmacy towns—and only then by ignoring various factors that would lead to a far greater population base using that pharmacy, such as hospitals, highways, and proximity to other cities—proves that his method is unreliable.

As a final matter, Plaintiffs misdirect again by trying to flip the burden on Defendants, arguing that "Defendants do nothing to show that Dr. Siegel's estimations of the population served by a given pharmacy is inaccurate." Resp. at 10. Defendants bear no such burden, but in any event Dr. Siegel himself acknowledged both of the primary shortcomings Defendants identified. ***First***, he conceded that he never considered the population of people passing through Milton, Williamson, Mount Gay-Shamrock, and Lesage on the major highways that pass through each of these towns. MOL at 9. ***Second***, he admitted that the relative location of hospitals like Cabell-Huntington Hospital, St. Mary's Medical Center, and the VA Medical Center in Huntington that serve regional, state-wide, or even interstate populations "is something that needs to be

[2] Ex. B at 37:23-38:5 ("Q. You made the judgement that it would not be appropriate to apply your 'oversupply' methodology to Huntington pharmacies because you couldn't get comfortable that you could identify the right population base for those pharmacies. Correct? A. Exactly.").

considered" as it relates to populations served—yet he did not do so. MOL at 10-11 (quoting Ex. B at 329:13-17). These concessions from Dr. Siegel himself demonstrate the unreliability of his opinions, and why this Court should exclude them.

Estimates about nationwide benchmarks. Dr. Siegel arbitrarily chose to base his benchmark on only the number of adults aged 20 and over who used a prescription opioid *in the past 30 days*, rather than the number who used opioids in the past year. When asked to explain why he chose that time period, Dr. Siegel admitted that the decision was motivated at least in part by the fact that he could not find different data—even though such data was readily available from the U.S. Department of Health and Human Services. *See* MOL at 12-13. Nevertheless, Dr. Siegel's arbitrary decision resulted in him undercounting the number of prescription opioid users in the country which, in turn, resulted in an artificially low benchmark that allowed Dr. Siegel to call many more opioid dosage units "oversupply" when, in fact, they were not. *See* MOL at 12-13.

Plaintiffs argue that, because Dr. Siegel thinks his calculation is correct, it should be admitted. Resp. at 12-13. As an initial matter, Plaintiffs are incorrect because Dr. Siegel's opinion must be based on more than his own "*ipse dixit*." *See General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997). But, more importantly, Plaintiffs overlook the fact that Dr. Siegel concedes methodological gaps in his reasoning. He arbitrarily attempted to adjust national averages to reflect a specific West Virginia population with no basis for doing so. Ex. B at 106:5-18. And he arbitrarily used a truncated set of opioid users (users in the last 30 days) on the false assumption that would pick up only chronic users, again with no rational basis for doing so. Ex. B at 151:15-20. The specific defects in his claimed methodology render it unreliable regardless of whether Dr. Siegel thinks it is correct.

C. Dr. Siegel's Opinions About "Oversupply" Are Unreliable

Plaintiffs offer no reason for this Court to conclude that Dr. Siegel's opinions about "oversupply" are, in fact, reliable. Indeed, their response largely obfuscates the critical fact that no one has ever conducted an analysis like Dr. Siegel's—for reasons that are unsurprising. As Defendants have noted, there is no medical or industry standard for determining "oversupply," nor does Dr. Siegel explain why his particular definition should be treated as reliable. Indeed, he conceded that no peer-reviewed study has ever used his methodology or anything analogous to identify an "oversupply" of opioids. Ex. B at 118:22-119:7. Dr. Siegel even admitted that his "oversupply" label is largely meaningless, because he has no way of identifying whether the allegedly oversupplied opioids were, in fact, subject to a legitimate prescription or going to a legitimate use. Ex. B at 109:4-15. As a result of these shortcomings, Dr. Siegel's opinion about a purported "oversupply" of opioids is, in fact, nothing more than his own say-so, and is not based on a reliable, established methodology. *See Joiner*, 522 U.S. at 146 (recognizing that "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert").

Plaintiffs take issue with Defendants' assertion that Dr. Siegel's calculation of "oversupply" is novel, and hinge their argument on one sentence from Dr. Siegel's report stating that the "'concept of evaluating the volume of opioids being supplied to a particular pharmacy in light of the population size for the location of the pharmacy is widely accepted as a means of identifying potential oversupply.'" Resp. at 6 (quoting Ex. A at 33). Tellingly, Dr. Siegel cites no authority for this proposition. But more fundamentally, he admitted that he could not identify any other use of his purported method for calculating "oversupply," outside of his report. Ex. B at 118:22-119:13. His method was instead wholly invented for litigation with no grounding for it outside the courtroom.

As a final matter, Plaintiffs falsely state that "McKesson itself has used the same methodology." Resp. at 7. McKesson has never calculated a national benchmark in the way Dr. Siegel did, and then used that benchmark to claim that every pill above that level was illegitimate. Only Dr. Siegel has done that, and only in this courtroom.

D. Dr. Siegel's Conclusions About Distributors' "Public Health Responsibilities" Are Improper Legal Conclusions And Are Unreliable

Characterizing Dr. Siegel's opinions as being about "responsibility" rather than a legal duty is a distinction without a difference. As Defendants pointed out, Dr. Siegel's opinion may avoid using the word "duty,"[3] but semantics aside, his opinion amounts to little more than an unsubstantiated belief that Distributors had a legal obligation to protect the public health by preventing "oversupply" through, among other means, performing "due diligence." *See* Ex. A at 26. He then goes on to conclude, based on his "oversupply" analysis, that Distributors failed in that duty. In other words, without any case or statutory support, Dr. Siegel has created a legal duty out of whole cloth merely for the purposes of this litigation. Plaintiffs tacitly admit that there is no real distinction between the so-called "responsibility" and a legal duty, when they recognize that Dr. Siegel "supports his opinions ***about the standard of care in the public health field*** ...." Resp. at 14 (emphasis added). Such opinions—regardless of what they are called—are inappropriate. *See United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) ("[O]pinion testimony that ***states a legal standard*** or draws a legal conclusion by applying law to the facts is generally inadmissible.") (emphasis added). But, even if Dr. Siegel's opinion were not an inappropriate legal conclusion, it would still be unreliable, because he readily admits that he has

[3] Dr. Siegel does use the word "duty" when describing his purported expertise, calling himself "an expert in . . . the public health *duties* of pharmaceutical companies and distributors. . . ." Ex. A at 7 (emphasis added). Regardless of whether he uses the word "duty" in the opinion section of his report, it is clear that "duty" and "responsibility" are the same to Dr. Siegel.

never before written about a "responsibility" of this nature, and he is not aware of any other publications (besides the "very general" industry documents he references) that outline the "responsibility" he opines about. MOL at 16.

Put another way, Plaintiffs' argument fails regardless of how it is framed. On the one hand, if Dr. Siegel is opining about "the standard of care in the public health field," Resp. at 14, then his opinion is an improper legal conclusion. But on the other hand, if he is merely providing personal anecdotes based on nothing more than a few industry publications, his opinion is unreliable and does not support his claimed "oversupply"-prevention duty. In both cases the result is the same—Dr. Siegel's purported opinion about a public health "responsibility" on the part of Distributors should be excluded.

CONCLUSION

For the foregoing reasons, this Court should exclude the testimony of Plaintiffs' "oversupply" expert Dr. Michael Siegel.

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Respectfully Submitted,

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CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that on this 20th day of November, 2020 the foregoing ***Reply Memorandum in Support of Defendants' Motion to Exclude the Expert Testimony of Dr. Michael Siegel*** was served using the Court's CM/ECF system, which will send notification of such filing to all counsel of record.

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